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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,659	10/05/2005	Yoshiji Yamada	050174	9383

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KRATZ, QUINTOS & HANSON, LLP
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EXAMINER

JOHANNSSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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01/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,659	Applicant(s) YAMADA ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 3, drawn to methods of genotyping and risk diagnosis comprising analysis of 2 or more of a group of 4 particular polymorphisms in the glycoprotein Ia, chemokine receptor 2, apolipoprotein C-III, and G-protein beta3 subunit genes. It is further noted that each combination of polymorphisms encompassed by the claims corresponds to a separate subgroup of Group I, as methods encompassing analysis of each subgroup do not share a special technical feature with each other, as discussed below.

Group II, claim(s) 2 and 4, drawn to methods of genotyping and risk diagnosis comprising analysis of 2 or more of a group of 4 particular polymorphisms in the tumor necrosis factor-alpha gene, the insulin receptor substrate-1 gene, and the glycoprotein Ibalpha gene. It is further noted that each combination of polymorphisms encompassed by the claims corresponds to a separate subgroup of Group II, as methods encompassing analysis of each subgroup do not share a special technical feature with each other, as discussed below.

Group III, claim(s) 5 and 7, drawn to kits and substrates comprising 2 or more nucleic acids of a group of nucleic acids "for analyzing" 4 particular polymorphism in the glycoprotein Ia, chemokine receptor 2, apolipoprotein C-III, and G-protein beta3 subunit genes. It is further noted that each combination of 2 or more nucleic acids encompassed by the claims corresponds to a separate subgroup of Group III, as the various combinations do not share a special technical feature with each other, as discussed below.

Group IV, claim(s) 6 and 8, drawn to kits and substrates comprising 2 or more nucleic acids of a group of nucleic acids "for analyzing" 4 particular polymorphisms in the tumor necrosis factor-alpha gene, the insulin receptor substrate-1 gene, and the glycoprotein Ibalpha gene. It is further noted that each combination of 2 or more nucleic acids encompassed by the claims corresponds to a separate subgroup of Group IV, as the

various combinations do not share a special technical feature with each other, as discussed below.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. Groups I and II are directed to the detection of different combinations of polymorphisms located in different genes, and thus do not share a technical feature that might constitute a special technical feature as set forth in PCT Rule 13.2. Similarly, the products of Group III relate to different polymorphisms than the methods of Group II, and the products of Group IV relate to different polymorphisms than the methods of Group I, such that no shared technical feature is present with regard to Groups III and II, or IV and I. It is noted that the nucleic acids of Group III are directed to detection of the polymorphisms recited in Group I, and that the nucleic acids of Group IV are directed to detection of the polymorphisms of Group II. However, Groups III-IV require only nucleic acids "for analyzing" the recited polymorphisms; thus, these Groups encompass, e.g., microarrays comprising all possible 10-mers, such as those exemplified by Brennan (US 5,474,796 A [12/1995]; see entire reference, particularly Example 4, col 9, lines 48-60), as such microarrays could be used "for analyzing" the reciting polymorphisms via well known methods. As Groups III-IV do not make a contribution over the prior art, the technical feature shared by Groups I and III, and II and IV, cannot constitute a special technical feature under PCT Rule 13.2. Thus, unity of invention is lacking with respect to Groups I-IV.

Further restriction requirement applicable to Group I-IV

3. As discussed in MPEP 1850, lack of unity of invention may exist within a single claim. In the instant case, Groups I-IV each encompass a multitude of distinct polymorphism combinations (set forth within each of claims 1-4) and nucleic acid combinations (set forth within each of claims 5-8). Each combination encompassed by the claims has a unique set of structural features and functional properties, such that the various combinations cannot be regarded as being "of a similar nature," and thus lack a special technical feature under PCT Rule 13.2 (see Annex B of the Administrative Instructions under the PCT). Thus, each of the polymorphism combinations encompassed by Groups I-II constitutes a separate subgroup, and each of the nucleic acid combinations of Groups III-IV constitutes a separate subgroup.

Accordingly, in addition to electing one of Groups I-IV, Applicant must further elect a single polymorphism combination from those encompassed by the claims if either of Group I or II is elected, or a single nucleic acid combination from those encompassed by the claims if either of Group III or IV is elected. **This is not an election of species. Applicant is advised that examination will be restricted to the elected combination.**

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/528,659
Art Unit: 1634

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long horizontal line extending to the right.

Diana B. Johannsen
Primary Examiner
Art Unit 1634